PTO/SB/08A (10-96)

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Sub	stitute f	or form	1449A/PTO	Complete if Known		
				Application Number	10/747,686	
INFOR	TAMS	ION	DISCLOSURE	Filing Date	December 30, 2003	
STATI	EME	NT B	Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
•				Group Art Unit	1615	
(use as many sheets as necessary)				Examiner Name	Fubara, Blessing M	
Sheet	1	of	10	Attorney Docket Number	P-2769-US9	

		U.S. Pater	nt Document	No. of Botostic or Applicant	Date of Publication of	Pages, Columns, Lines, Where Relevant
xaminer nitials*	Cite, No. 1	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY	Passages or Relevant Figures Appear
BF	Α	4,990,538		Harris et al.	February 5, 91	
1	В	5,788,964		Baral et al.	August 4, 98	
	С	5,650,425		Biegnon et al.	July 22, 97	
	D	4,696,949		Toivola et al.	Sept 29, 87	
	E	5,491,173	.	Toivola et al.	Feb. 13, 1996	
	F	5,571,534		Jalonen et al.	Nov. 5, 1996	
1	G	5,605,700		DeGregorio et al.	Feb. 25, 1997	
	Н	5,595,722		Grainger et al.	Jan. 21, 1997	
	ı	5,599,844		Grainger et al.	Feb. 4, 1997	
	J	5,629,007		Audia et al.	May 13, 1997	
V	κ	5,635,197		Audia et al.	June 3, 1997	
BF	L	5,595,985		Labric	Jan. 21, 1997	

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Examiner Initials*	Cite No. 1		gnPatent Document Kind Code ⁵ Number ⁴ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	J.e
BF	м	wo	98/58634	DEGREGORIO, et al	December 30, 98	<u> </u>	
1	N	ЕР	415 623 A2	Harris et al	March 6, 1991		
	0	EP	616 529 BI		September 28, 94		
	Р	EPC	095875	•	Dec 7, 1995		
V	Q	wo	95/26720	Biegon et al	Oct 12, 1995		
BF	R	wo	0008001	Huebner, et al	Feb 17, 2000		

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				Group Art Unit	1615	
(use as many sheets as necessary)			ets as necessary)	Examiner Name	Fubara, Blessing M	
Sheet	2	of	10 .	Attorney Docket Number	P-2769-US9	

	T	U.S. Patent Document	U.S. PATENT DOCUMENTS		Pages, Columns, Lines,
xaminer nitials*	Cite, No.	Number Kind Cod (if known)		Date of Publication of Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear
BF .	s	4,329,364	Neri et al.	May 11, 1982	
	τ	4,474,813	Neri et al.	Oct. 2, 1984	
	υ	6,080,877	Swindell et al	June, 2000	
	V	6,265,448	Steiner et al	July 24, 2001	
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	AB	4,996,225	Toivola et al	Feb 26, 1991	·
	AC	5,811,120	Gibson et al	Sept 22, 1998	
V	AD	5,972,383	Gibson et al	Oct 26, 1999	
BF	AE	4,418,068	Jones	Nov 29, 1983	

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Examiner Initials*	Cite, No.	Forei	gnPatent Docum Kind (Number (if kno		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	70
BF	AF	wo	94/12162		Warri et al	June 9, 1994		
BF	AG	wo	99/56739		Steiner et al	November 11, 1999		
BF	AH	wo	00/47214		Healey et al	August 17, 2000		
BF	Al	wo	96/09046		Audia et al	March 28, 1996		
BF	AJ	EP	0 670 162		Gibson et al	Sept 6, 1995		
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		NON PATENT LITERATURE DOCUMENTS	
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BF	AK	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	
	AŁ	Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	
	AM	Gershanovich et al., " A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	
	AN	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	
	AO	Gingrich et al., "Metastatic Prostrate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.	
	AP	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
	AQ	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.	
	AR	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 16H: 1-8.	
	AS	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin D Analogue Ro24-553 1 for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	
	AT	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.	
	AU	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO002117653.	
	AV	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	
	AW	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	
$\sqrt{}$	AX	Schneider Martin R. et al. "Nonsteroidal Antiestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265,	
BF	AY	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	

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		NON PATENT LITERATURE DOCUMENTS	
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BF	AZ	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antogonist (LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	BA	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	ВВ	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of Toremifenein Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	ВС	Hietanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.	
<u> </u>	BD	Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	_ <u>i</u>
	BE .	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	
	BF	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	
	BG	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by 17β-Estadiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc., Vol. 63 March 1979, pages 351-357.	
	вн	Neubauer et al., "Endocrine and Antiprostatic Effects of Raloxifene (LY156758) in the Male Rat", The Prostate 23, 1993, pages 245-262.	
	ВІ	Perry "High Dose Toremifene for Estrogen and Progesterone Receptor Negative Metastatic Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast Cancer Res Treat - 1995; 26(1): 25-40	
·	BJ	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39, 1999, pages 305-309.	
	вк	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt) 1998 Mar; 12(3 Suppl 5): 28-31.	
	BL	Pyrhönen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study", British Journal of Cancer, 1997, 76(2), pages 270-277.	
·	вм	Shenfeld et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer, pages 467-477	
V	BN	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Int. J Cancer: 57, 224-228 (1994)	
BF	во	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs", Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	

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STATEMENT BY APPLICANT				First Named Inventor	STEINER, Mitchell S.	
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		NON PATENT LITERATURE DOCUMENTS	
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BP BP		"Chemoprevention Of Prostate Cancer: Guidelines For Possible Intervention Strategies", Journal of Cellular Biochemistry, Supplement 16H:140-145 (1992).	
	BQ	Awoniyi Caleb A. et al. "Neonatal Exposure To Coumestrol, A Phystoestrogen, Does Not Alter Spermatogenic Potential In Rats", Endocrine, vol. 7, no. 3, 337-341, December 1997.	
	BR	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.	1
	BS	Brandes LJ et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paragdigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.	
	ВТ	Chang William Y et al. "Estrogen Receptor-\(\beta\): Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
	BU	Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5-6): 888-94.	
	BV	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto- Oestrogens", British Journal Of Urology (1998). 82. 560-563.	
	BW	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	
	вх	Miyata E et al. "Effects Of Tamoxifen, An Antiestrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testerone Do Not Support An Estrogen Role In Testerone Promotion", Prostate 1997 Apr 1;31(1)9-13.	
	BY	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dorsal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
	BZ	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate"., Am J Clin Oncol 1996 Oct; 19(5):500-3.	
	CA	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate 1995 May; 26(5): 270-4.	
	СВ	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression In The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801-1809, 1997)	
$\overline{\bigvee}$	CC	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-α (Er-α) And β (Er-β) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract" Steroids 63: 498-504, 1998, Elsevier Science Inc.	
BF	CD	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1		T²
BF CE		"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-β", Endocrinology Vol. 138, No. 3, (1997).	
	CF	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 16H:138-139 (1992).	
	CG	Anttila M et al. "Pharmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
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	CI	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	C1	Griffiths K. et al. "Further Insights Into Endocrine Disease - Diet and Prostate Disease" An IPHC Teaching Programme.	
	СК	Horton J et al. "Tamoxifen In Advanced Prostate Cancer: An ECOG Pilot Study", Prostate 1988; 12(2):173-7.	
	CL	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	СМ	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	-
	CN	Kuiper George G. J. M. et al. "Comparison Of The Ligand Binding Specificity And Transcript Tissue Distribution Of Estrogen Receptors α and β", Endocrinology Vol. 138, No. 3, 863-870 (1997).	
	СО	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifene, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)	
	СР	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	CQ	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	
BF	CR	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	

Examiner /Blessing Fubara/ Signature	Date Considered	01/07/2007
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		"New Research Approaches In The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research. December 1998	
	CT	Boehm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.	
	CU	Bonkhoff H et al. "Estrogen Receptor Expression In Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	CV	Buelke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.	
	CW	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
	IOV	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses In The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	
	CY	Landstrom M, et al. "Inhibitory Effects Of Soy and Rye Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
	CZ	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	
	DA	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction In Rats And Rabbits:, Toxicol Sci 1998 Feb; 41(2):199-207.	
V	DB	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	
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BF DD		Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overview of Diet Cancer 6928-6975 (1995)			
	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Ov Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.				
	DF	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antogonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.			
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·	DH	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).			
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Exan Signa	niner ature	/Blessing Fubara/	Date Considered	01/07/2007

^{*} EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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. Substitute for form 1449A/PTO	Com	Complete if Known		
	Application Number	10/747,686		
INFORMATION DISCLOSURI	Filing Date	December 30, 2003		
STATEMENT BY APPLICAN	First Named Inventor	STEINER, Mitchell S.		
	Group Art Unit	1615		
(use as many sheets as necessary)	Examiner Name	Fubara, Blessing M		
Sheet 9 of 10	Attorney Docket Number	P-2769-US9		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc		Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
NEW DQ FROM HERE		"GTx begins next phase of clinical trials for prostate cancer." Expert Rev Anticancer Ther. 2001 1(3) 326	
BF DR		Bostwick David "Prospective Origins of Prostate Carcinoma" American Cancer Society 1996	
	DS	Bostwick, David G. et al "Reversibility of Prostatic Intraepithelial Neoplasia: Implications for Chemoprevention" Eur. Urol 1999: 35:492-495	
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	DU	Hard, Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl: CD(BR) Rats" Cancer Research 53, 4534-4541, October 1, 1993	٠
·	DV	Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983	
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Examiner Signature	/Blessing Fubara/	Date Considered 01/07	/2007 .

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	Substitute	for form	1449A/PTO	Complete if Known		
				Application Number	10/747,686	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	December 30, 2003	
				First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615	
(use as many sheets as necessary)			ets as necessary)	Examiner Name	Fubara, Blessing M	
Sheet	10	of ·	10	Attorney Docket Number	P-2769-US9	

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	itials* No.1 publisher, city and/or country where published.				
BF	EF	Schneider, et al (1991) "Effect of zindoxifene on experimental prostatic tumors of the rat." J. Cancer Res Clin Oncol. 117 (1) 33-6.			
BF	EG	Ip MM, et al (1980) "Funtionality of estrogen receptor and tamoxifen treatment of R3327 Dunning rat prostate adenocarcinoma." Cancer Res 40 (7) 2188-93.			
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